IN THE

Supreme Court of the United States

OCTOBER TERM, 1972

No. 72-394

CASPAR W. WEINBERGER, SECRETARY OF HEALTH, EDUCATION AND WELFARE, AND CHARLES C. EDWARDS, COMMISSIONER OF FOOD AND DRUGS, PETITIONERS

v.

HYNSON, WESTCOTT AND DUNNING, INCORPORATED

On Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

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MEMORANDUM FOR USV PHARMACEUTICAL CORPORATION, AMICUS CURIAE

USV Pharmaceutical Corporation is the petitioner in No. 72-666 (*USV Pharmaceutical Corp.* v. *Weinberger*), one of the cases before this Court arising under the Federal Food, Drug, and Cosmetic Act of 1938[1] with which the instant

[1] 52 Stat. 1040, *as amended*, 21 U.S.C. §§ 301 *et seq.*

case has been consolidated.[2] The purpose of this memorandum is to bring to the Court's attention the relationship between the instant case and an administrative proceeding to which USV is a party, related to the proceedings involved in No. 72-666, and which is now pending before the Commissioner of Food and Drugs.[3]

1. The USV administrative proceeding to which we refer, like the instant case, arises under Section 505(e) of the Act.[4] It was initiated by the Commissioner's publication of a proposal to revoke approval of the new drug applications held by USV for some of the products involved in the declaratory judgment proceedings before this Court in No. 72-666.[5] A final order of revocation, entered by the Commissioner without a hearing on the ground that USV had not attempted affirmatively to establish the existence of a material factual issue requiring a hearing, was set aside by the Court of Appeals for the District of Columbia Circuit for failure to conform to the requirements of administrative due process."[6] The government decided not to

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[2] 409 U.S. — (1973). The other three cases are *Hynson, Westcott & Dunning, Inc.* v. *Weinberger*, No. 72-414, *CIBA Corp.* v. *Weinberger*, No. 72-528, and *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, No. 72-555.

[3] *Drugs for Human Use Containing Rutin et al.*, Dkt. No. FDC-D-112 (FDA).

[4] 52 Stat. 1053, *as amended*, 21 U.S.C. § 355(e).

[5] The initiation of the administrative proceeding precipitated the commencement of the declaratory judgment action by USV.

[6] *USV Pharmaceutical Corp.* v. *Secretary of HEW*, 466 F.2d 455, 462 (D.C. Cir. 1972). To avoid confusion with the decision of the Court of Appeals for the Fourth Circuit in No. 72-666, the D.C. Circuit decision will hereafter be cited as "*USV II*". That opinion is reproduced in the appendix to the petition for certiorari in No. 72-666 (pp. 36a-49a).

petition for certiorari to review the decision,[7] and the matter is again before the Commissioner pursuant to the judgment of the court of appeals remanding for further proceedings.[8]

The issue principally discussed in the opinion of the D.C. Circuit was the Commissioner's misapplication of summary judgment principles so as to require USV, the respondent in the revocation proceeding, to justify in the first instance its request for a hearing on the Commissioner's bare-bones proposal to revoke approval of its new drug applications.[9] The Court recognized that a summary judgment procedure may be used in Section 505(e) proceedings "in appropriate circumstances", but ruled that the provision in that statute giving an NDA holder "opportunity for hearing" before approval of his NDA is revoked "does restrict the application of that procedure to cases in which no material factual issue is presented and a hearing would be a hollow formality."[10] In deciding whether a material factual issue was presented with respect to the proposed revocation of approval of USV's new drug applications, the court of appeals continued, the Commissioner "was not an impartial arbiter of the contentions of opposing parties, but was himself the moving party undertaking to support his own pro-

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[7] Resp. Mem. on Petition for Certiorari, p. 4 n. 6, *USV Pharmaceutical Corp.* v. *Weinberger*, No. 72-666.

[8] The Commissioner has *sua sponte* stayed the proceedings before him pending the decision of this Court in No. 72-666 (letter dated October 17, 1972, from HEW Ass't Gen. Counsel Hutt to counsel for USV).

[9] The two remaining errors were the absence of adequate findings and conclusions to support the final order (466 F.2d at 461-62), and the Commissioner's arbitrary and unexplained failure to give USV "an opportunity to submit additional evidence or plead over when its request for a stay [pending disposition of the declaratory judgment proceedings in the district court] was denied" (*id.* at 462.)

[10] *Id.* at 460 n.5.

posed order." [11] Moreover, the statutory basis for revocation of approval was observed to be "new information, together with the evidence available when approval was originally granted." [12]

The court held that certain "limited steps" would therefore be "basic to administrative fairness":[13]

> "In this situation • • • it was incumbent upon the Commissioner, before calling upon the petitioner for additional evidence establishing a right to a hearing, to state facts and reasons showing at least prima facie that the evidence before him raised no material issue of fact which would justify a hearing. • • • Before calling upon the petitioner to answer, the Commissioner, as the moving party, had an obligation to present at least a prima facie case for denial of a hearing. [Citations omitted.] Only after such a presentation could the Commissioner fairly impose upon petitioner the heavy sanctions of 21 C.F.R. § 130.14." [14]

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[11] *Id.* at 461.

[12] *Ibid.*

[13] *Ibid.*

[14] *Ibid.* The court buttressed its conclusion that "administrative fairness" so requires by referring to the well-established doctrine under Rule 56 of the Federal Rules of Civil Procedure that a party moving for summary judgment "may not, by the bare assertion that he is entitled to summary judgment, shift to his opponent the burden of establishing the contrary" (*ibid.*). Also cited were this Court's decisions in *Greene* v. *McElroy*, 360 U.S. 474, 496 (1959) that one of the "principles • • • relatively immutable in our jurisprudence • • • is that where governmental action seriously injures an individual, and the reasonableness of the action depends on fact findings, the evidence used to prove the Government's case must be disclosed to the individual so that he has an opportunity to show that it is untrue", and in *Southern R. Co.* v. *Virginia*, 290 U.S. 190, 197 (1933) that "an administrative officer may [not] be empowered, without notice or hearing, to act with finality upon his own opinion and ordain the taking of private property."

In the USV proceeding, the D.C. Circuit found, no such prima facie case for denial of a hearing had been presented by the Commissioner, and a final revocation order consequently could not be entered without a hearing merely because USV had not attempted to demonstrate the existence of a material factual issue justifying a hearing. Both the Commissioner's notice of intent to initiate a proceeding [15] and the subsequent notice of opportunity for hearing [16] merely "parroted the language of the statute without reference to any evidence." [17] Although the original notice of intent referred to reports of expert panels rendered in the NAS-NRC Drug Efficacy Study,[18] these reports "were cryptic and conclusory, without any statement of supporting facts." [19] The final order revoking approval of USV's new drug applications was accordingly set aside,[20] because, *inter alia*, "such an application of the Commissioner's summary judgment rule is not in harmony with the principle of the rule and is fundamentally unsound and unfair." [21]

2. Throughout its brief in the instant case the government appears to assume that, contrary to the decision of the D.C. Circuit in *USV II*, respondent Hynson was *obligated* to come forward with evidence in response to the Commissioner's bare-bones notice of opportunity for hearing (A.

[15] A. 290-91. ("A. —" refers to the Joint Appendix in the instant case and those, including No. 72-666, with which it has been consolidated.)

[16] A. 293-97.

[17] 466 F.2d at 461.

[18] The nature and function of these panels is described at pp. 16-17 of the Brief for Petitioners in No. 72-555, *Weinberger* v. *Bentex Pharmaceuticals, Inc.*

[19] 466 F.2d at 461. The reports were reproduced in full earlier in the court's opinion (*id.* at 458).

[20] *Id.* at 462.

[21] *Id.* at 461.

12-14) if it wished to avoid entry of a final order of revocation without any hearing. The correctness of that assumption, however, does not seem to be in issue in this case, since, unlike USV, Hynson—whether obligated or not—did in fact come forward with such evidence.[22]

Thus, this case does not tender—as would the D.C. Circuit's *USV II* decision had the government brought it here for review—the question of which party, the Commissioner or the respondent, has the *initial* burden of coming forward with a showing on the existence or non-existence of a factual issue requiring a hearing. It is our understanding that respondent Hynson will rely upon the *USV II* decision as an alternative ground for affirmance of the judgment below. We would stress, however, the substantial difference described above between the posture of the instant case and that of the USV administrative proceeding when the Commissioner's final revocation orders were respectively entered. In the light of this difference, a decision by the Court that the Commissioner was entitled to enter a final revocation order against Hynson without a hearing in the circumstances of this case could not be taken as *sub silentio* overturning or undermining the ruling in *USV II*, or questioning the applicability to Section 505(e) revocation proceedings of the general principles of constitutional and administrative law on which the D.C. Circuit relied.

This memorandum is therefore filed out of an abundance of caution in order to safeguard USV's interests, in the event of a decision adverse to Hynson, by making explicit

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[22] Nor does the government appear to view the correctness of its assumption as properly before this Court for decision. The point is not specifically argued in the government's brief, and, indeed, the only explicit reference to it is the single observation (Pet. Br. 22), offered without explanation or justification, that the Commissioner's summary judgment regulation "does no more than place upon the party demanding a hearing the responsibility to present 'the evidence needed to make out a *prima facie* case.' "

at this time the distinction between the instant case and *USV II*, where the decision in USV's favor has become final by operation of law as a consequence of the governments's determination not to seek certiorari.

Respectfully submitted,

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